

PART 429—DRUGS COMPOSED WHOLLY OR PARTLY OF INSULIN**Subpart A—General Provisions**

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AUTHORITY: 21 U.S.C. 352, 356, 371.

CROSS REFERENCES: For other regulations in this chapter concerning insulin drugs, see also §200.15.

SOURCE: 39 FR 11750, Mar. 29, 1974, as amended at 40 FR 13497, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions**§ 429.3 Definitions and interpretations.**

For the purpose of the regulations in this part:

(a) The term *act* means the Federal Food, Drug, and Cosmetic Act, as amended.

(b) The term *Secretary* means the Secretary of Health and Human Services.

(c) The term *Commissioner* means the Commissioner of Food and Drugs.

(d) The term *U.S.P.* means the official United States Pharmacopeia, including supplements thereto.

(e) The term *N.F.* means the official National Formulary, including supplements thereto.

(f) The definitions and interpretations of terms contained in section 201 of the act shall be applicable to such terms when used in the regulations in this part.

(g) The term *insulin* means the active principle of pancreas which affects the metabolism of carbohydrate in the animal body and which is of value in the treatment of diabetes mellitus.

(h) The term *insulin injection* means the insulin injection recognized in the U.S.P.

(i) The term *protamine zinc insulin suspension* means the protamine zinc insulin suspension recognized in the U.S.P.

(j) The term *globin zinc insulin injection* means the globin zinc insulin injection recognized in the U.S.P.

(k) The term *isophane insulin suspension* means the isophane insulin suspension recognized in the U.S.P.

(l) The term *insulin zinc suspension* means the insulin zinc suspension recognized in the U.S.P.

(m) The term *prompt insulin zinc suspension* means the prompt insulin zinc suspension recognized in the U.S.P.

(n) The term *extended insulin zinc suspension* means the extended insulin zinc suspension recognized in the U.S.P.

(o) The term *master lot* means a quantity (which is purified and which has been mixed in one container so as to be homogeneous) of:

(1) A concentrated solution of insulin; or

(2) The insulin-containing solids, in amorphous or crystalline form, derived from one or more such solutions.

(p) Except as provided in §429.41(c), the term *batch* means a quantity of a drug, in labeled packages, of uniform composition and intended for administration without further change, in which the sole insulin-containing ingredient is a single dilution (which has been mixed in one container so as to be homogeneous) of:

(1) A single master lot or part thereof; or

(2) A mixture of two or more master lots or parts thereof; except that such term means a portion of such quantity when certification of such portion is requested.

(q) The term *master lot mark* means an identifying mark or other identifying device assigned to a master lot by the manufacturer thereof.

(r) The term *batch mark* means an identifying mark or other identifying device assigned to a batch by the manufacturer thereof.

[39 FR 11750, Mar. 29, 1974, as amended at 39 FR 40285, Nov. 15, 1974]

Subpart B—Packaging and Labeling

§ 429.10 Packaging.

Each batch shall be packaged in immediate containers of colorless transparent glass. Such containers shall be closed with a substance through which successive doses may be withdrawn by hypodermic needle without removing the closure or destroying its effectiveness. The containers and closures shall be sterile at the time the containers are filled and closed. The composition of the containers and closures shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor prescribed in applicable standards of strength, quality, and purity. The shape of the containers shall be cylindrical, except that the cross-section of the containers for isophane insulin suspension containing less than 100 U.S.P. Units of insulin per milliliter shall be a rounded square, and the shoulder of the containers for insulin zinc suspension, prompt insulin zinc suspension, or extended insulin zinc suspension containing less than 100 U.S.P. Units of insulin per milliliter shall be hexagonal.

[39 FR 11750, Mar. 29, 1974, as amended at 39 FR 40285, Nov. 15, 1974]

§ 429.11 Labeling.

Each package from a batch that has been certified in accordance with the regulations in this part shall bear, on its label or labeling as hereinafter indicated, the following:

(a) On the outside wrapper or container and the immediate container of the retail package:

(1) The batch mark of such batch;

(2) The potency of the drug in terms of the U.S.P. Units of insulin per milliliter; and

(3) The statement “Expiration date _____,” the blank being filled in with the date on which the certificate applicable to such batch expires with respect to such package, as provided in § 429.45(b)(1).

(b) On the outside container or wrapper of the retail package, the statement “Keep in a cold place, avoid freezing.”

(c) If the batch contains 40 or 100 U.S.P. Units of insulin per milliliter, on the circular or other labeling of the retail package:

(1) A statement that the treatment of diabetes mellitus is an individual problem and that the use of the drug, the time of its administration, and the number of daily doses and the quantity of each, as well as diet and exercise, are problems which require direct and continuous medical supervision;

(2) A statement explaining that the volume of the dose depends on the number of units of insulin per milliliter stated on the label, and that the patient should understand the meaning of the volume markings on the syringe;

(3) A description of a practicable method for sterilizing the needle and syringe before use;

(4) A description of the technique of withdrawal from the vial and the use of an antiseptic on the stopper, and a caution against the removal of the stopper;

(5) A description of the technique for cleansing, and the use of an antiseptic on the site of injection;

(6) A statement that failure to comply with the techniques described in paragraphs (c) (3), (4), and (5) of this section may lead to infection of the patient;

(7) A statement that injection should be subcutaneous, at a different site from that of the preceding injection, and a caution against intravenous or intramuscular use;

(8) An explanation of hypoglycemia and its relation to overdosage, omission of meals, illness, and infection;